

REMARKS

I. Status of the Claims

By this paper new claims 24 to 31 are added. No new matter is added by this amendment. Support for the new claims can be found in, for example, claims 9-15 of the application as filed.

II. Interview Summary

On April 15, 2010 Applicants conducted a telephone interview with Examiner Kosar. The Examiner is thanked for his very helpful consideration during the interview.

Applicants discussed their intention to file a Request for Pre-Appeal Brief Review. The Examiner indicated that he would remove finality of the October 16, 2009 Office Action, such that a Request for Pre-Appeal Brief Review would not be necessary. Applicants indicated that they would still like to present their arguments on the record, and that would therefore file this paper to set forth Applicants position regarding the prior rejections of the claims.

The possibility of adding method of treatment claims was also discussed during the interview. Such claims were previously withdrawn following election of composition claims in response to the Restriction Requirement of July 14, 2005. Examiner Kosar indicated that he would consider such method claims in the present case. The Examiner is thanked for his accommodation in this regard. New claims 24 to 31, which are directed to methods of treatment, are presented herein.

III. Previous Rejections of the Claims

In the Final Office Action of January 22, 2009, claims 1 and 17 were rejected under 35 U.S.C. §102(a) as allegedly being anticipated by Welch *et al.* (2003), Neuropeptide Treatment of Genetic and Acquired IBD and Concomitant Brain Activation in Areas Abnormal in Autism, Society for Neuroscience Abstract, Program No. 318.5, (hereinafter "Welch").

- *Welch is 102(a) art*
- *Welch was published in 2003*

In addition, claims 1, 8, 17, and 21 were rejected 35 U.S.C. §103(a) as allegedly being obvious over Hollander U.S. Pub. 2006/0105939 (hereinafter “Hollander”) in view of an NIH News Alert (The Use of Secretin to Treat Autism - Internet document dated 08/17/2001), Swain (E. Swain, Pharmaceutical and Medical Packaging News, 1999) and Pierce (PIERCE Technical Resource Sheet TR0043.0; Protein Stability and Storage; June 2003).

- *Hollander is 102(e) art*
- *The earliest possible effective date of Hollander is October 3, 2002*

There were no other rejections in the Final Office Action of January 22, 2009.

On July 22, 2009 Applicants filed a Response to the Final Office Action of January 22, 2009, including a Declaration under 37 C.F.R. § 1.131 (the “ July 2009 Declaration”). The July 2009 Declaration provided evidence showing that the subject matter of the rejected claims was reduced to practice by the inventors prior to the publication of Welch in 2003, and prior to the earliest effective date of Hollander of October 3, 2002, and that therefore neither reference qualifies as prior art to the rejected claims

On October 16, 2009, the Office issued a further Final Office Action, which stated the following:

“The Declaration filed on July 22, 2009 under 37 CFR 1.131 has been considered, but is ineffective to overcome the Hollander reference or Welch. Applicants affidavit now indicated that reduction to practice occurred “at least prior to October 3, 2003,” however this has already been established by Applicant in the two previous declarations, which clearly stated reduction to practice occurred “at least prior to August 17, 2001.” Thus, it is apparent that applicant had reduced it prior to October 3, 2002, having already declared it had occurred at least 14 months earlier in each of the previous declarations. In the previous declarations Applicant provided a statement that the lab notes predate August 17, 2001, however the instant Application was filed March 11, 2004. Again, as before, there is no evidence of diligence between the earliest date of asserted conception (prior to 8/17/01) and the date of filing (3/11/04). Furthermore, it is noted that Applicant’s ‘conception’ in the previous declarations is equivalent to ‘reduction to practice’ in that Applicant made the

compositions now claimed. Thus, the rejections are maintained for the reasons of record.”

In an interview with Examiner Kosar on January 11, 2010, Applicants asserted that the 131 Declaration was effective to overcome the cited art because it demonstrated reduction to practice of the claimed invention prior to the dates of the cited art references, and that there was therefore no need to demonstrate diligence. As indicated in the Interview Summary of January 25, 2010, no agreement was reached on this point.

On February 16, 2010, Applicants filed a Response to the Final Office Action of October 16, 2009, stating that 131 Declaration was effective to overcome Welch and Hollander prior art because it demonstrated reduction to practice of the claimed invention prior to the effective dates of the cited art.

Contrary to the statements in the Final Office Action, neither of the two prior 131 Declarations asserted reduction to practice at least prior to August 17, 2001. Instead, both of the prior Declarations asserted conception of the claimed invention at least prior to August 17, 2001. These prior Declarations were deemed ineffective to overcome the prior art on the basis that the showing of diligence was insufficient.

Because of this Applicants performed a further assessment of the evidence of prior invention, resulting in the filing of the July 2009 Declaration – which provides additional evidence not present in the prior Declarations and shows reduction to practice of the claimed invention prior to October 3, 2002.

In asserting that the July 2009 Declaration is ineffective to antedate the cited art, the Final Office Action of October 16, 2010 stated on page 2: “Again, as before, there is no evidence of diligence between the earliest date of asserted conception (prior to 8/17/01) and the date of filing (3/11/04).”

- *The assertion that the July Declaration is ineffective because there is no showing of diligence is incorrect*

37 CFR 1.131(b) and the MPEP state that the factual evidence presented in a 131 affidavit must show EITHER reduction to practice prior to the effective date of the reference, OR conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application (see below).

§ 1.131 AFFIDAVIT OR DECLARATION OF PRIOR INVENTION
(emphasis added)

“(b) The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, OR conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application. Original exhibits of drawings or records, or photocopies thereof, must accompany and form part of the affidavit or declaration or their absence must be satisfactorily explained.”

MPEP 715.07. III. THREE WAYS TO SHOW PRIOR INVENTION
(emphasis added)

“As discussed above, 37 CFR 1.131(b) provides three ways in which an applicant can establish prior invention of the claimed subject matter. The showing of facts must be sufficient to show:

(A) >(actual)< reduction to practice of the invention prior to the effective date of the reference; OR

(B) conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to a subsequent (actual) reduction to practice; OR

(C) conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to the filing date of the application (constructive reduction to practice).”

The July 2009 Declaration established reduction to practice prior to the effective date of the cited references. Thus, there was no requirement for a showing of diligence.

During the January 11, 2010 Interview with Examiner, as stated in the Examiner's Interview Summary of January 25, 2010, during the interview "[t]he Examiner additionally indicated that the 1.131 declaration was insufficient to 'swear behind' the 102(a) rejection, as it was by Applicant and others, and a Katz declaration would be needed..."

- *The assertion that a Katz declaration is required is incorrect*

As set forth in the MPEP, where Applicants are co-authors of a publication cited against them under 35 U.S.C. 102(a), they may overcome the rejection either by filing a declaration under 37 C.F.R. § 1.131 to antedate the reference or by filing a declaration under 37 C.F.R. § 1.132 (see below).

MPEP 715.01(C) REFERENCE IS PUBLICATION OF APPLICANT'S OWN INVENTION (emphasis added)

I. < CO-AUTHORSHIP

Where the applicant is one of the co-authors of a publication cited against his or her application, he or she may overcome the rejection by filing an affidavit or declaration under 37 CFR 1.131. **ALTERNATIVELY**, the applicant may overcome the rejection by filing a specific affidavit or declaration under 37 CFR 1.132 establishing that the article is describing applicant's own work. An affidavit or declaration by applicant alone indicating that applicant is the sole inventor and that the others were merely working under his or her direction is sufficient to remove the publication as a reference under 35 U.S.C. 102(a). In re Katz, 687 F.2d 450, 215 USPQ 14 (CCPA 1982).

The July 2009 Declaration establishes reduction to practice of the claimed invention prior to the publication of Welch and prior to the earliest possible effective date of Hollander, in satisfaction of the requirements 37 CFR 1.131(b). Thus, there is no requirement for a Katz declaration under 37 CFR 1.132.

IV. New Method of Treatment Claims

As set forth above, the rejections of the composition claims under 102(a) and 103(a) are overcome, such that the composition claims are allowable. Accordingly, Applicants submit that the new "method of treatment" claims presented herein are also allowable.

CONCLUSION

Applicant respectfully requests reconsideration and allowance of the pending claims. If it will facilitate prosecution of this application, the Examiner is invited to contact the undersigned at the telephone number below.

Respectfully submitted,

Dated: April 16, 2010

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